K101245

SEP 17 2010

SPECIAL 510(K) PREMARKET SUMMARY

UltraSeal ID

This summary of the Special 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 for UltraSeal ID.

Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Diane Rogers
Title:	Regulatory Affairs Manager
Telephone:	800-552-5512 x4491, 801-553-4491
FAX:	801-553-4609
Date Summary Prepared:	May 3, 2010

Name of the Device

Trade Name:	UltraSeal ID
Regulation Number:	CFR 872.3765
Device:	Pit and Fissure Sealant and Conditioner
Device Classification:	II
Classification Product Code:	EBC

Legally Marketed Predicate Device to Which Equivalence is Claimed

Ultradent's UltraSeal XT plus (K050959) and Seal-n-Glo (K050959) are similar in that they all are Pit and Fissure Sealants. Seal-n-Glo and UltraSeal ID contain fluorescent attributes to identify the product using a compact blacklight.

UltraSeal XT plus is manufactured by Ultradent Products Inc. 505 West 10200 South, South Jordan, UT 84095

Delton® Illuminating Pit and Fissure Sealant "Seal-n-Glo" is manufactured by Dentsply International, Susquehanna Commerce Center West, 221 West Philadelphia Street, Suite 60, York, PA 17405-0872

Brief Description of testing performed

The following tests were conducted during the R & D phase on UltraSeal ID and compared to UltraSeal XT plus (K993846) and Delton® Illuminating Pit and Fissure Sealant Seal-n-Glo (K050959). Test results are included in this 510(k).

a. **Hardness** – This test shows the hardness of the bond. We prefer to stay within our competitors range.
b. **Compressives** – This test shows different forces on the resin. On the Strength side, we prefer higher numbers and mid range numbers on Modulus.
c. **Shrinkage** – This is the percentage that the resin will shrink after curing. We prefer low numbers
d. **Shear Peel** – This test shows higher adhesion. A high number compared to our competitors is acceptable and preferred.
e. **Film Thickness** – We prefer lower numbers in this test to show how thin we can apply the material
f. **Viscosity/Rheometry** – We prefer the viscosity of the product to be low so it will flow into crevices.
g. **Sorption/Solubility** – This test shows how much water the resin absorbs. We prefer lower reading on this test

Clinical Summary

A detailed Clinical Summary is included in this submission. It contains literature which we have selected that supports our claims for the safety and efficacy of UltraSeal ID.

Product Description: UltraSeal ID is a 58% filled, light-cure, radiopaque, methacrylate-based, thixitropic resin sealant. UltraSeal ID technology provides visual verification for marginal retention with the use of a UV light, upon placement and at recall visits. A pit and fissure sealant and conditioner is a device composed of resin, such as polymethylmethacrylate, intended for use primarily in young children to seal pit and fissure depressions (faults in the enamel) in the biting surfaces of teeth to prevent cavities.

Indications for Use: Use UltraSeal ID for prophylactic sealing of pits and fissures. It may also be used for microrestorative or "initial layer" of composite restorations.

	UltraSeal ID	UltraSeal XT plus	Seal-n-Glo
Indications For Use	Use UltraSeal ID for prophylactic sealing of pits and fissures. It may also be used for microrestorative or "initial layer" of composite restorations.	Use UltraSeal ID for prophylactic sealing of pits and fissures. It may also be used for microrestorative or "initial layer" of composite restorations.	Delton® Illuminating Pit and Fissure Sealant is indicated for preventive sealing of pits and fissures in the primary and secondary dentition in combination with the acid-etch technique
Delivery System	Syringe	Syringe	Syringe
Curing	Light Cured	Light Cured	Light Cured
Black light illumination	**Yes**	No	**Yes**
% Filled	**58%**	58%	**38%**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Diane Rogers
Regulatory Affairs Manager
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

SEP 17 2010

Re: K101245
Trade/Device Name: UltraSeal ID
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit and Fissure Sealant and Conditioner
Regulatory Class: II
Product Code: EBC
Dated: August 13, 2010
Received: August 18, 2010

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101245

SEP 17 2010

Statement of Indications for Use

510(k) Number (if known): _____

Device Name: UltraSeal ID

Indications for Use: Use UltraSeal ID for prophylactic sealing of pits and fissures. It may also be used for microrestorative or "initial layer" of composite restorations.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101245